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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,603	11/12/2003	Stephen L. Warren	1195.284US1	5852

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,603	WARREN ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks, all filed 05/10/07 is acknowledged.

Applicant's election with traverse of Group I (claims 1-17 & 19) and Applicant's election with traverse of election of species of bioadhesive polymer (a) polyacrylic acid; film-forming polymer – HPMC and election of pharmaceutical – antiglaucoma agent, in the reply filed on 05/10/07 is acknowledged. The traversal is on the ground(s) that "The subject matter of the claims in Groups I and II can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner" and that "the search of the claims in Group I would likely identify art relevant to the claims in Group II". This is not found persuasive because as stated in the Restriction requirement, Group I is drawn to local delivery of a pharmaceutical, whereas Group II is drawn to systemic delivery of a pharmaceutical. The different groups would require different modes of operation, delivery and function. Additionally, the groups are different, as evidenced by their distinct classification. Both groups would require separate searches and there is no expectation that the searches would be coextensive in scope. Thus, this creates and undue search burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18 and 20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/10/07.

Claims 1-20 are pending in this action. Claims 18 and 20 have been withdrawn (based on non-elected invention). Claims 1-17 and 19 are being examined in this office action. Claims 1-17 and 19 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 recites "*a combined amount of up between about...*". It is unclear whether Applicants intended to recite "a combined amount of *up to* between about" or alternatively, "a combined amount *of between*". Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky *et al.* (U.S. Pat. No. 5,800,832) in view of Bowman *et al.* (U.S. Pat. No. 6,372,245) OR Wong *et al.* (U.S. Pat. No. 6,331,313).

The instant invention is drawn to a method for delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises: a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers; a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-

adhesive layer, or associated with both the bioadhesive and non-adhesive layers; wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.

Tapolsky *et al.* ('832) teach a water-soluble, bioerodible pharmaceutical delivery device for application to mucosal surfaces. Methods for treating mucosal surfaces by applying the bilayer film to the treatment site for drug delivery and protection is also disclosed. The device comprises an adhesive layer and a non-adhesive backing layer and the pharmaceutical may be provided in either or both layers. Upon application, the device adheres to the mucosal surface, providing drug delivery and protection to the treatment site (see Abstract). The bioerodible pharmaceutical delivery device adheres to mucosal surfaces for the localized delivery of pharmaceutical compounds (col. 1, lines 1-23); (col. 3, lines 45-48).

The delivery device for application to mucosal surfaces provides protection of and delivery of pharmaceutical to the site of application, surrounding tissues and other bodily fluids, having an effect on residence time, with minimal discomfort and ease of use (col. 3, lines 23-28).

In one embodiment, the pharmaceutical delivery device comprises a bilayer film disk having an adhesive layer and a backing layer, both water-soluble, having the pharmaceutical in either or both layers (col. 3, lines 28-33). The adhesive layer comprises a film former such as hydroxypropylmethyl cellulose (HPMC), hydroxypropyl cellulose (HPC), or hydroxylethyl methylcellulose (HEMC), alone or in combination and a bioadhesive polymer such as polyacrylic acid (PAA), polyvinyl pyrrolidone (PVP) or sodium carboxymethyl cellulose, alone or in combination. The non-adhesive backing layer comprises polymers such as HPMC (col. 3,

lines 29-48). The bioadhesive polymers have good and instantaneous mucoadhesive properties in a dry, film state (col. 5, lines 38-61).

According to Tapolsky *et al.*, the water-soluble bioerodible device finds particular use in the localized treatment of body tissues, diseases or wounds which may have moist surfaces, such as the mouth and other types of mucosal surfaces (col. 3, lines 51-58). It is taught that the device is an appropriate vehicle for the local as well as systemic delivery of pharmaceutical, given its thinner, flexible form (col. 4, lines 46-50).

The thickness of the device ranges from 0.05 mm to 1 mm and more preferably, from 0.1 to 0.5 mm (col. 8, lines 13-20). This range meets Applicant's claimed range of between about 0.1 mm to about 0.5 mm (instant claim 14).

Pharmaceuticals are incorporated in the device and comprise 0.001 to 30% by weight of the device and more preferably between 0.005 and 20% by weight (col. 8, lines 1-5). This range meets Applicant's claimed range of between about 0.005 and 20% by weight (instant claim 13).

Tapolsky *et al.* do not teach antiglaucoma agents.

Bowman *et al.* ('245) teach controlled release medicament systems for delivery of pharmaceutical drugs for the treatment of ocular conditions, comprising a bioerodible polymer, whereby suitable medicaments that can be delivered include antiglaucoma agents (see col. 9, lines 45-54) and Abstract. Specific active agents are disclosed at column 9, line 55 – col. 11, line 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as the antiglaucoma agents of Bowman *et al.* within

the delivery device of Tapolsky *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Bowman *et al.* teach controlled release systems that are beneficial for treating conditions of the eye and teach that effective and useful active agents include antiglaucoma agents. The expected result would be an enhanced method of drug delivery for effectively combating infections of the eye.

* * * * *

The teachings of Tapolsky *et al.* are discussed above. Tapolsky *et al.* do not teach antiglaucoma agents.

Wong *et al.* ('313) teach biocompatible controlled release delivery devices that are used to deliver active agents, such as antiglaucoma agents (col. 1, line 55 – col. 2, line 3). The delivery can be localized or systemic (col. 3, lines 41-50). Specific active agents are disclosed at column 10, line 55 – col. 12, line 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as the antiglaucoma agents of Wong *et al.* within the delivery device of Tapolsky *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Wong *et al.* teach controlled release delivery devices, useful for treating eye disorders (i.e., blindness) and teach that effective and useful active agents in their device include antiglaucoma agents. The expected result would be an improved method for delivering drugs to mucosal surfaces, such as ocular surfaces, for reducing infections and disorders of the eye.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner
Art Unit 1615
July 23, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER

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